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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/484,704	01/18/00	HENRICKSON K	650053.91126

EXAMINER	
SIEW, J	
ART UNIT	PAPER NUMBER
1656	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/484,704	HENRICKSON ET AL.	
	Examiner	Art Unit	
	Jeffrey Siew	1656	

-- Th MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,12,20,23 and 34-36* is/are pending in the application.

4a) Of the above claim(s) *6,12,20,23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 6/6/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/484704 is acceptable and a CPA has been established. An action on the CPA follows.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 34-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 5,744,299 in view of Wu (EP0418960 A2 March 27, 1991).

Claims 34-36 are drawn to detecting visual infection by exposing nucleic acid with 5' and 3' primer at unequal concentrations and amplifying and determining amplification by hybridizing a protein linked probe identical to viral sequence. Claim 35 is drawn to claim 34 with the added limitation of specific primer ratios.

Claims 1,10 & 11 of U.S. Patent No. 5,744,299 are drawn to exposing cDNA to primer pairs which amplify human parainfluenza virus 1 and detecting by probe specific for HN that is labeled with enzyme.

Wu et al teach a method of performing polymerase chain reaction using unequal primer concentration in which primer pairs is at least 2:1 (see abstract). They teach a polymerase reaction in which is denaturation is performed thirty times at 95C.

One of ordinary skill in the art would have been motivated to apply Wu et al's primer ratios to the method claims of US5,744,299 in order to successfully amplify the virus nucleic acid. As Wu et al teach that unequal primer ratio of 2:1 would lead to effective amplification, it would have been prima facie obvious to apply Wu et al's ratios to method claims of US5,744,299 in order to maximize the amplification of viral nucleic acid.

5. Claims 34 & 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,015,664 in view of Sninsky et al (US5,176,995 Jan. 5, 1993).

Claims 34 & 36 are drawn to detecting visual infection by exposing nucleic acid with 5' and 3' primer at unequal concentrations and amplifying and determining amplification by hybridizing a protein linked probe identical to viral sequence.

Claim 1 U.S. Patent No. 6,015,664 are drawn to exposing cDNA to unequal primer concentration pairs for HPIV1,2,3 RSV A& B and Influenzae A & B.

Claim 1 of US 6,015,664 is not drawn to hybridization with protein linked probe.

Sninsky et al teach detection by hybridizing with a probe that is complementary to conserved nucleic acid sequence to genome of virus (see col. 15 line 40-45) and using biotin labeled probes for detection (see col. 16 line 9).

One of ordinary skill in the art would have been motivated to apply Sninsky et al's teaching of biotin labeled probes to the method claim of US6,015,664 in order to quickly detect amplified virus. As biotin label probes allow rapid colorization, it would have been prima facie obvious to apply Sninsky et al's teaching of biotin probes to the detection method claim 1 in order to rapidly detect viral sequences without the use of harmful radioactivity.

6. Claims 35 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 5,744,299 in view of Sninsky et al (US5,176,995 Jan. 5, 1993) by Wu (EP0418960 A2 March 27, 1991).

Claim 35 is drawn to claim 34 with the added limitation of specific primer ratios.

Claim 1 of 6,015,664 and Sninsky et al (US5,176,995 Jan. 5, 1993) are described previously.

Claim 1 is not drawn to the specific primer ratios.

Wu et al teach a method of performing polymerase chain reaction using unequal primer concentration in which primer pairs is at least 2:1 (see abstract). They teach a polymerase reaction in which is denaturation is performed thirty times at 95C.

One of ordinary skill in the art would have been motivated to apply Wu et al's primer ratios to method claims of US6,015,664 in order to successfully amplify the virus nucleic acid. As Wu et al teach that unequal primer ratio of 2:1 would lead to effective amplification, it would have been prima facie obvious to apply Wu et al's ratios to method claims of US6,015,664 in order to maximize the amplification of viral nucleic acid.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karron et al (J. Clinical Micro vol. 32 no. 2 pp. 484-88 1994) in view of Sninsky et al (US5,176,995 Jan. 5, 1993).

Karron teach PCR rapid detection of HPIV-3 of HN gene using RT-PCR (see whole doc. esp. abstract).

Karron do not teach protein linked probe nor unequal primer concentration.

Wu et al teach a method of performing polymerase chain reaction using unequal primer concentration in which primer pairs is at least 2:1 (see abstract). They teach a polymerase reaction in which is denaturation is performed thirty times at 95C.

Sninsky et al teach detection by hybridizing with a probe that is complementary to conserved nucleic acid sequence to genome of virus (see col. 15 line 40-45) and using biotin labeled probes (see col. 16 line 9).

One of ordinary skill in the art would have been motivated to apply Wu et al's primer ratios to Karron's method in order to successfully amplify the virus nucleic acid. As Wu et al teach that unequal primer ratio of 2:1 would lead to successful amplification, it would have been prima facie obvious to apply Wu et al's ratios to Karron's method in order to maximize the amplification of viral nucleic acid.

Moreover, one of ordinary skill in the art would have been motivated to apply Sninsky et al's teaching of biotin labeled probes to Karron's detection method in order to quickly detect

amplified virus. As biotin label probes allow rapid colorization, it would have been prima facie obvious to apply Sninsky et al's teaching of biotin probes to the Karron's detection method in order to rapidly detect viral sequences without the use of harmful radioactivity.

SUMMARY

9. No claims allowed.

CONCLUSION

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can best be reached on Monday through Thursday from 6:30 a.m. to 4 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703)-308-1152.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist for Technology Center 1600 whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official

Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Fax (703) 308-4556 or (703) 308-4242.

Jeffrey Siew

August 12, 2001